Department of Health and Human Services Public Health Service

Food and Drug Administration
Rockville, MD 20857

MAR 13 2012

Re: Dexilant
Patent Nos. 6,462,058, 6,664,276, and 6,939,971
Docket Nos. FDA-2009-E-0238
FDA-2009-E-0237
FDA-2009-E-0239

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the patent term extension applications for U.S. Patent Nos. 6,462,058, 6,664,276, and 6,939,971 filed by Takeda Pharmaceutical Company Limited under 35 U.S.C. § 156. The patents claim Dexilant (previously Kapidex) (dexlansoprazole), which were assigned new drug application (NDA) 22-287.

In the June 23, 2011, issue of the Federal Register (76 Fed. Reg. 36929), the Food and Drug Administration published its determination of the product's regulatory review periods, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before December 20, 2011, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Douglas P. Mueller
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